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BEYER WEAVER & THOMAS LLP				
P.O. BOX 778				
BERKELEY, CA 94704-0778				
EXAMINER				
GORDON, BRIAN R.				
ART UNIT		PAPER NUMBER		
1743				

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/889,548

Examiner

Brian R. Gordon

Applicant(s)

JOHNSON ET AL.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

## A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14 and 59-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 59-66 and 78 is/are rejected.
- 7) ☒ Claim(s) 4, 14, 67-77, 79-88 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2003 has been entered.

### ***Response to Arguments***

Applicant's arguments filed December 15, 2003 have been fully considered but they are not persuasive. Applicant has amended 1 and 59 by describing the manifold as being "a single unit fluid distribution manifold". Applicant also states on pages 18-19 of the remarks: Accordingly, the hybrid valve apparatus provides a single-unit fluid distribution manifold and single valve assembly that enables aspiration into and dispensing from a dispensing orifice of a discrete path, a primary passage portion of which extends at least partially through the manifold. In the present invention, both the aspiration conduit and the dispensing conduit are contained in a relatively rigid, single-unit or one-piece manifold structure (28) applied for fluid aspiration and distribution of the sample slugs. This arrangement is beneficial in that there is not only a substantial reduction of components, but there is a reduction in the number of interconnection interfaces and flexible tubing. For precision fluid dispensing, energy can be dissipated through turbulent interfaces and through flexible tubing, causing inaccuracies in such

fluid dispensing. By providing a rigid, single unit the aspiration and dispensing energy of the actuators can be concentrated on the aspiration and dispensing procedures.

Briefly, while the single-unit manifold (28) may be originally constructed from multiple plate members (e.g., 63-66, Figs. 4-6), for construction purposes, they will be rigidly mounted together to form the single-unit manifold 28."

Applicant asserts that the manifold of the instant invention is a "single-unit" or "one piece" however the examiner fails to locate support for such an assertion within the text of the specification that the device is "one piece" or a "single-unit". The term "single unit" has not been found to be defined as more than one element mounted together.

Applicant's arguments are not commensurate in scope with that of the specification. For the specification discloses on page 6:

"In another aspect of the present invention, the manifold device may be (may be what?) by a plurality of laminated plate members which collectively define the body of the manifold. At least two plate members are fixedly mounted together in a manner cooperatively defining at least one of the aspiration conduits and the dispensing conduits."

Pages 10-11 of the specification disclose:

"The **manifold device 28 includes a fluid aspiration conduit 30** having a first aspiration port 31 in fluid communication with the aspiration source 21. On an opposite end of the aspiration conduit 30 is a second aspiration port 32 in selective fluid communication with the valve assembly 27 to selectively aspirate a liquid sample slug

from the reservoir 23 into a discrete sample path 33 when the valve assembly 27 is in the aspiration condition. The **manifold device 28 further includes a fluid dispensing conduit 35** having a first dispensing port 36 in fluid communication with the dispensing source 22, and a second dispensing port 37 in selective fluid communication with the valve assembly 27."

Page 21 discloses:

"In another aspect of the present invention, the manifold device 28 is comprised of a plurality of stacked plate members 63-66 which collectively cooperate to channel the sample fluids from the reservoir wells to the designated test sites 25, via the valve assembly 27."

The manifolds as disclosed above are not "one piece" or "a single unit" as asserted by applicant. The manifold assemblies of the instant invention are comprised of a plurality of elements however applicant is allowed to refer to the components collectively as the manifold, but the components are not truly "a single unit" or "one-piece" as applicant has defined within the remarks. If applicant insists that the term "single unit" be define as given in the remarks, the term "single-unit" would actually be considered new matter for there is no support within the specification to support the device being "a single unit" or "one-piece".

The paragraphs from applicant's specification clearly establish that the manifolds are not "one-piece" or a "single-unit" as asserted by applicant.

The examiner asserts that a number of elements collectively may be considered a single unit. As such for the purpose of examination the examiner interprets the term

"single unit" as a number of elements considered collectively in combination as one unit.

As such, the examiner asserts that the components of Kenny collectively meet the limitation of a "single unit" as claimed by applicant.

For the reasons given herein and below the examiner hereby maintains the previous rejection of the previous Office Action.

In view of applicant's amendment to the specification the objection to the specification as stated in the previous office action is hereby withdrawn.

### ***Specification***

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification discloses on page 6:

"In another aspect of the present invention, the manifold device may be by a plurality of laminated plate members which collectively define the body of the manifold."

It appears as if a verb or adjective is missing between the words "be" and "by".

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1-3, 5-6, 66 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant acknowledged that it is not intended for the actuators to be claimed as element of the invention. However after further review of the claim the examiner has determined that the actuators are required in the structure of the device for in claims 1 66, and 78, it is recited "...a first aspiration port **in** fluid communication with the aspiration actuator,.... and a first dispensing port **in** fluid communication with the dispensing actuator. As drafted the claim requires the respective ports of the manifold be in communication with the respective actuators. If applicant intends for the actuators not to be considered or required it is suggest that the claims be amended to recite "port **for** communication with.." or "port **capable of** communicating with..." to express the idea that the ports may be in communication with the respective actuators.

Applicant also amended the claim to add a phrase to express the functionality of the device in terms of the relationship of the valve assembly (positively claimed) and a reservoir, dispensing orifice, and a fluid communication structure (all not positively claimed). It is unclear if applicant intends for the dispensing orifice and the fluid communication structure to be considered as elements of the invention. The claim as presently drafted does not positively claim the components as elements of the invention. For the purpose of examination, the examiner has considered the components as elements of the invention, however the claim should be amended to positively claim the components as elements of the invention.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 59, 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Kenny US 4,461,328.

Kenney discloses a pipette device comprises one or more pipette tubes for aspirating and dispensing liquid.

In operation, the device 2 is positioned with pipette tubes inserted into wells 6 containing an aqueous liquid (not shown). A negative pressure (aspiration actuator) is exerted, for example, by sucking in on tube 38 which causes the aqueous liquid contained in wells 6 to be drawn into pipette tubes 4 until the liquid reaches the hydrophobic filter sheet 20 which stops the upward movement of liquid in tubes 4. At this juncture, each pipette tube 4 is completely full, containing an exact predetermined amount of liquid. The device 2 is then removed from tray 8 and is moved to, for example, another tray 8 into which it is desired to discharge the liquid contained in pipette tubes 4. Tubes 4 are aligned with the wells into which their contents are to be discharged and a positive pressure (dispensing actuator), for example, by mouth is applied to tube 38 causing air to pass through the filter sheet 20 and discharge the contained liquid.

It will be understood that the vacuum applied will be consistent with the pore size of the hydrophobic filter sheet so that the pressure differential between the atmospheric pressure and the pressure in the vacuum chamber above the filter sheet will be insufficient to cause the aqueous liquid to enter the filter sheet. This presents no problem since the pressure differential can be small for satisfactory operation compared



to the pressure differential necessary to cause the aqueous liquid to enter the filter sheet of a given pore size. Thus an operator's lung suction providing a pressure differential of about 3 p.s.i. is more than adequate for operation, whereas it takes a pressure differential of about 19 p.s.i. to cause liquid to enter the pores of a typical hydrophobic filter sheet having a pore size of 0.2 microns.

As shown in FIGS. 5 and 6, flexible hose 38 may be connected to a **conventional prior art vacuum-pressure device 50 which has a two-way solenoid valve 52 which can connect either a pressure line 54 or a vacuum line 56 to flexible hose 38.** The position of valve 52 is controlled by a toggle switch 58 which is connected to the solenoid valve 52 by lines 60 and 62 and in turn is connected to a source of power by lines 64 and 66.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 5-10 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny as applied to claims 1-3, 59, 63-65 above, and further in view of by Naono US 4,120,661.

Kenny does not disclose the configuration of the switching valve as comprising a rotor stator configuration.

Naono discloses a rotating valve body and a fixed valve body, said rotating body and fixed body having radial surfaces in sliding contact. The radial surface of the rotating body is provided with one or more internal sampling outlet ports arranged on the circumference of a circle having a center coincident with the axis of the rotating body. The side wall of said rotating body is provided with one or more external sampling inlet ports. Pairs of unlike ports are connected by ducts in said rotating body. The external sample inlet ports are connected to a sample tube, or tubes or sample suction tube or tubes which rotate together with the rotating valve body. The radial surface of

the fixed valve body is provided with a single internal sample inlet port located the same distance from the axis as the internal sample outlet ports. The internal sample inlet port is directly linked to two ports in the sidewall of the fixed valve body by two ducts which join together at the internal inlet, said ducts being connected to a reagent tank via a sampling pump, changeover valve, reagent pump, and a reaction beaker via said changeover valve.

The rotating body 32 (rotor) initially rotates (as the body/stator 31 remains still) so as to establish a condition as shown in FIG. 3. That is to say, so that internal sample outlet ports 34a, 34b, etc. do not align with the internal sample inlet port 39. In this condition, samples 50a, 50b, etc. contained in sample tubes 37a, 37b, etc. (reservoir) flow out through feed lines 38a, 38b, etc. Next, the ducts 35a, 35b, etc. are filled with respective samples as follows: The rotating body 32 commences to turn stepwise so that internal sample outlet ports 34a, 34b, etc. register with internal sample inlet port 39 successively. As each outlet port (34a, etc.) registers with inlet port 39, the sampling pump 46 comes into operation and draws sample into ducts 40 and 41, said small amount of sample being allowed to drain into a waste bath (not shown) via feed line 45 and the flow path changeover valve 47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ a changeover valve (switching valve) structure as taught by Naono to allow for access or switching the communication of fluid flow between conduits within a system.

***Allowable Subject Matter***

5. Claims 4, 67-77, 79-88 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
5. Claims 66 and 78 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
7. The following is a statement of reasons for the indication of allowable subject matter: The prior art of Naono does not teach nor fairly suggest that the transverse cross-sectional area of the primary passage is from about  $0.2 \text{ mm}^2$  to  $0.8 \text{ mm}^2$  or that the device includes a digitally regulated hydraulic pressure system in fluid communication with the dispensing actuator for precision operation thereof.

***Conclusion***

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700